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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,360	12/15/2003	Adam P. Dicker	032599-054740	6009
50828	7590	01/28/2008		
DAVID S. RESNICK 100 SUMMER STREET NIXON PEABODY LLP BOSTON, MA 02110-2131			EXAMINER KWON, BRIAN YONG S	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 01/28/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/737,360

Applicant(s)

DICKER ET AL.

Examiner

Brian S. Kwon

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/25/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7-10,12-14,17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) is/are withdrawn from consideration.
- 5) ☐ Claim(s) is/are allowed.
- 6) ☒ Claim(s) 1,5,7-10,12-14,17 and 18 is/are rejected.
- 7) ☐ Claim(s) is/are objected to.
- 8) ☐ Claim(s) are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. .
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: <u> </u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u> </u> | 6) <input type="checkbox"/> Other: <u> </u> |

DETAILED ACTION

Status of Application

1. Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114. Claims 24, 25 and 28 are currently pending for prosecution on the merits.
2. Acknowledgment is made of applicant's filing of Argument filed 01/29/2007. By the amendment, claim 6 has been cancelled; claims 1, 10 and 13 have been amended; and claims 17 and 18 have been newly added. Claims 1, 5, 7-10, 12-14 and 17-18 are currently pending for prosecution on the merits of the case.
3. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Claim Objections

4. Claims 1, 5, 7 and 8 are objected to because of the following informalities: "and/or" should be corrected as either "and" or "or". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 5, 7-10, 12-14 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over EL-Naggar et al. (US 2003/0045562) in view of Hallahan et al. (USP 5962424), Stewart et al. (USP 6887474) and Nichtberger (USP 6136804).

EL-Naggar teaches a use of a composition comprising COX2 inhibitor, anti-platelet agent such as aspirin, and antioxidant in combination of radiotherapy for the treatment of various diseases including cancer (abstract; para. [0001]; claim 2), wherein the compounds or

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components are administered concurrently (at the same time) or sequentially in any order or at different points in time, so as to provide the desired therapeutic effects (para. [0010]). EL-Naggar also teaches the use of tissue plasminogen activator and the GPIIb/IIIa antagonist such as abciximab, eptifibatide, tirofiban, lamifiban, lefradafiban, sibrafiban, orbofiban and xemilofiban, as suitable agent for the combination therapy (para. [00009]).

Nichberger is being supplied as a supplemental reference to demonstrate the use of clopidogrel or clopidogrel bisulfate (Plavix) as functional equivalent to GPIIb/IIIa receptor antagonist (column 17, lines 56-58 and column 23, line 5).

Hallahan is being supplied as supplemental reference to demonstrate routine knowledge in using ionizing radiation for the treatment of solid tumor (abstract; column 2, line 55; column 5, line 66).

Stewart is being supplied as supplemental reference to demonstrate routine knowledge in using anti-platelet drug (e.g., anti-GPIIb/IIIa agent and clopidogrel) in treating solid tumor masses including small cell lung carcinoma (column 7, lines 6-13; column 4, lines 12-18; column 11, line 39; column 13, line 67)

The teaching of El-Naggar differs from the claimed invention (i) mainly in the use of said combination in the treatment of specific cancer such as solid tumor, namely glioma or lung carcinoma and (ii) the use of specific anti-platelet agent such as clopidogrel or clopidogrel bisulfate (Plavix) and (iii) the use of ionizing radiation.

However, one having ordinary skilled in the art would have a reasonable expectation of success that El-Naggar's composition would be useful in the treatment of the claimed solid tumor in light of the cited references in combination. Furthermore, it would have been obvious to

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substitute said GIIb/IIIa receptor antagonist with clopidogrel or clopidogrel bisulfate because these agents were art-recognized functional equivalents at the time of the invention was made in the pharmaceutical art. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Furthermore, above references in combination make clear that ionizing radiation therapy is routinely utilized in the treatment of solid tumor and solid tumor such as lung carcinoma, particularly non-small cell lung carcinoma, is routinely managed by radiation therapy as well as anti-platelet agent.

Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

6. No Claim is allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Primary Patent Examiner
AU 1614

A handwritten signature in black ink, appearing to be 'Brian Kwon', written over the printed name and title.